RFP-NIAID-DMID-NIHAI2013178
Amendment #2

"*PHASE 1 CLINICAL TRIAL UNIT FOR THERAPEUTICS AGAINST INFECTIOUS DISEASES*"

Amendment Issue Date:	February 7, 2014
Proposal Due Date/Time:	**March 20, 2014** at **3:00** P.M., local time **[Changed]**
Issued By:	Aileene Mitchell Ford Contracting Officer OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3214, Bethesda, Maryland 20892-7612
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Offerors must acknowledge receipt of this Amendment on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.

The date specified for receipt of proposals HAS been extended.

1. This amendment revises *FAR Clause 52.216-22*, Indefinite Quantity (October 1995)

d. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract November 30, 2024.

Is revised to read as follows;

Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to

the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after the final active task order.

2. **Attachment 3, Statement of Work, dated September 9, 2013,** is revised to remove the following sentence under **2**. Activities for Task Area B, H. Insurance.

Product liability insurance will not be supported under this contract.

3. To access SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS, use the web link below. If you are still unable to access this form you may request a copy from the Contracting Officer identified on the cover page of the subject solicitation.

http://oamp.od.nih.gov/DGS/FORMS/sectionk_508.pdf

THIS AMENDMENT ALSO PROVDIES CLARIFICATION TO VARIOUS QUESTIONS

4. **QUESTION**: "Can you please also confirm that for case study B-1 this should be base[d] on 1 subject since there are none mentioned as there are for B-2 and B-3?"

ANSWER: Please see ATTACHMENT 6, Section I. *SCOPE*. As stated therein, the scope of Sample Task Order B-1 is for protocol development. There is no protocol execution associated with Sample Task Order B-1, and Offerors should propose a sample size based on their expertise as part of the protocol development.

5. **QUESTION**: In which proposal volume are proposal responses for the Small Business Subcontracting Plan Extent of Small Disadvantaged Business Participation and Past Performance Data to be located?

ANSWER: In the Business Proposal.

6. **QUESTION**: In Attachment 3, page 9 of 12, Section E(2)b, the RFP indicates that contractor will collaborate and coordinate with SDCC and Protocol Team and states " . . . provide Final Clinical Study Report to the COR." Attachment 3, page 6 of 12, item B.3.b states "… providing clinical trial data . . . to the Sponsor for use in the CSR." Item E.1.b of Attachment 3, page 9 of 12, states that contractor will "provide independent statistical expertise to perform data analysis." In Attachment 7, under II.B, item 26 lists Final CSR as a deliverable for Task Area B. In Attachment 8,on page 7 of 10, item C.15.e states ". . . providing information to the Final Clinical Study Report."

   a. For Sample TOs B-2 and B-3, is contractor expected to write and publish the CSR based on study conduct, SDCC-provided clinical trial data and contractor-provided statistical analysis? Or just provide input.

   ANSWER The Contractor shall collaborate and coordinate with the Protocol Team and the SDCC to prepare the CSR. The Contractor will be responsible for all deliverables per the delivery schedule.

   b. Will the SDCC provide TLFs for the CSR, or will it just transfer data for use by the contractor's statistician for preparation of TLFs and other statistical analysis?

   ANSWER The SDCC will provide the Tables, Listings, and Figures (TLF).

c. Will SDCC receive PK or other clinical research laboratory data and provide the data to contractor for inclusion in the CSR?

ANSWER The SDCC will review PK and other clinical research laboratory data. The Contractor shall collaborate and coordinate with the Protocol Team and the SDCC to prepare the CSR.

d. Will SDCC provide quality assurance activities for the research laboratory data management system?

ANSWER: No. The Offeror is responsible for all aspects of the data until data is provided to the SDCC.

7. **QUESTION**: Will the Contractor be able to use the DMID centralized clinical specimen barcoding and tracking system for all studies?

ANSWER: Yes, the Contractor will be able to use the DMID centralized clinical specimen barcoding and tracking system for all studies.

8. **QUESTION:** Regarding Attachment 9, page 2 of 4, #2 Task Area B, Items C3, C6, C7: It is our understanding that Clinical Monitoring is not in the scope of this RFP (See Attachment 3, page 7 of 12, Section B.6 where it indicates clinical monitoring will be carried out by the NIAID CROMS contractor). Do these items refer to Quality Management or Clinical Monitoring? Please confirm whether the Government wants Offerors to propose the costs of performing the Clinical Monitoring in Sample Task Orders B-2 and B-3 or just plan for coordination with the NIAID CROMS contractor who will perform the monitoring?

ANSWER: Attachment 9, page 2 of 4, #2 Task Area B, Items C3, C6, and C7 are in reference to planning and accommodating clinical monitoring visits to be carried out by the NIAID CROMS contractor.

9. **QUESTION**: Sample Task Order B-1-Attachment 6-Item II.A calls for the development of Case Report Forms. Attachment 9, page 2, Task Area B, B1 assumes 2 CRF revisions. Attachment 3, page 5 Item B.1.b appears to state that the SDCC will design data collection forms. Please confirm that the response for Sample Task Order B-1 should include the development of Case Report Forms.

ANSWER: Yes, the response for Sample Task Order B-1 should include the development of Case Report Forms.

10. **QUESTION:** In Attachment 3 page 10, F.2.a. "Inpatient Clinical Research Facilities - Is the Government's expectation that all Phase I units used under this contract will be Joint Commission accredited?

ANSWER: Yes

11. **QUESTION**: In Attachment 3 page 10, F.2.a. "Inpatient Clinical Research Facilities - What does the Government consider an accreditation equivalent to Joint Commission for inpatient research facilities?

ANSWER: Equivalent accreditations would be an accreditation that has the same requirements/standards as Joint Commission.

12. **QUESTION**: In Attachment 9, page 2 of 4, Section 4.1.G states "Assume four (4) new concepts are developed annually."

a. Will the initial concept ideas be identified by the Government and then developed by the Contractor or will the Contractor identify and develop all 4 concepts?

ANSWER: Concepts will be identified by the Government and developed by the Contractor.

13. **QUESTION**: For purposes of the Sample Task Orders, does the Government intend for the Contractor to provide shipping and transport for Clinical Trial Agents from the repository to the clinical site?

ANSWER: No.

14. **QUESTION**: On page 91 in the Alternate I language of FAR Clause 52.215-20 there is a provision that says, "The format specified in paragraph L.2.c.4 Certified Cost or Pricing Data, Subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission of cost data. Submission of all other certified cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408."

a. Paragraph L.2.c.4 does not appear to have a Subparagraph 3. Please clarify this reference?

ANSWER: Paragraph L.2c.4 "**Alternate I** (October 2010) of FAR Clause **52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data** (October 2010)" is deleted in its entirety and replace with the following:

Alternate I (October 2010) of FAR Clause **52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data** (October 2010). As prescribed in 15.408(l)(and see 15.403-5(b)(1)),substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision: (b)(1) The offeror shall submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in the following format:

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished. Submission of all other certified cost or pricing data shall be in accordance with table 15-2 in *FAR 15.408*.

b. Assuming we use the NIH Excel spreadsheet provided as Attachment 19 in section J, please confirm this will meet the requirements of Table 15-2 as it has in other NIH solicitations?

ANSWER: Yes, please use Attachment 19.

15. **QUESTION**: In Attachment 3 page 10, F.2.a. "Inpatient Clinical Research Facilities - For clinical research units Joint Commission standards only address informed consent. Is it the Government's expectation that the Phase I units will meet other Joint Commission requirements? If so can the Government target which Joint Commission requirements apply?

ANSWER: There are different programs with different standards. The appropriate program will depend on the type of facility being proposed.

16. **QUESTION**: In the description of Task Area B in Attachment 3, page 7 of 12, Section B.7.a (Safety Reporting) indicates participation in SMC and DSMB meetings. Can the Government further define the expected participation in terms of role of contractor/subcontractor personnel participating?

ANSWER: Participation in SMC and DSMB meetings include: review of draft SMC and DSMB reports and participation in SMC and DSMB open session teleconferences.

17. **QUESTION**: In the description of Task Area B in Attachment 3, page 9 of 12, Section E.1.b, can the Government confirm whether the Offeror is responsible for interim (as relevant) and final analysis for each Task Order awarded.

ANSWER: The Contractor shall collaborate and coordinate with the Protocol Team and the SDCC in the analysis of interim and final clinical trial data including submission, receipt, collation and interpretation of clinical trial data.

18. **QUESTION**: In attachment 8, page 7 of 10, do items 15(e) and 15(f) refer to Bioanalytical Laboratory Analysis activities or to overall Project activities?

ANSWER: Items 15(e) and 15(f) refer to the overall project activities as listed under Section 3.2.C.

19. **QUESTION:** In Attachment 3 page 10, F.2.a. "Inpatient Clinical Research Facilities - For clinical research units Joint Commission standards only address informed consent. Is it the Government's expectation that the Phase I units will meet other Joint Commission requirements? If so can the Government target which Joint Commission requirements apply?

ANSWER: There are different programs with different standards. The appropriate program will depend on the type of facility being proposed.

20. **QUESTION:** Regarding RFP-NIAID-DMID-NIHAI2013178 Amendment #1, Answer to Question #2: The Government's answer regarding the SDCC stated: "The SDCC is the clinical trial data repository and is responsible for conducting protocol data analysis and any subsequent post hoc analysis."

a. This answer appears to conflict with the SOW language in Item E(1)b of Attachment 3 page 6 of the RFP, which states that the contractor will "provide independent statistical expertise to perform data analysis." Does the answer provided in Amendment #1 above supersede this language in the RFP? Please clarify which statistical analysis, if any, the Government wants offerors to account for in our proposals?

ANSWER: The offeror is expected to provide the statistical expertise to allow the SDCC to complete programming and perform the actual execution of the data analysis (programming, feeding in the data, etc.) will be done by the SDCC.

21. **QUESTION:** Please advise as to the most helpful way we can demonstrate yearly costs.

ANSWER: Offerors should propose yearly cost for Task Area A. In addition, offerors should also propose cost on Sample Task Orders B1, B2 and B-3 in their entirety for each of the seven (years 1-7) year ordering period.

For Example,

Total Cost of Performing Sample task Order B.3 (Regardless of period of performance)
If Sample Task Order issued in Year 1 =$100,000
In Year 2=$101,500
In year 3=$103,000
In Year 4=$104,500